Epogen®, Procrit®, Retacrit® (epoetin alfa) Injection

When requesting Epogen®, Procrit®, Retacrit® (epoetin alfa) injection for non-oncology anemia, the individual requiring treatment must be diagnosed with one of the following FDA-approved indications and meet the specific coverage guidelines and applicable safety criteria for the covered indications.

FDA-approved Non-oncology Indications

- Anemia associated with chronic kidney disease (CKD) in individuals on dialysis and individuals not on dialysis
- Anemia associated with zidovudine use in HIV-infected patients
- Pre-surgical use to reduce allogeneic blood transfusions

Coverage Guidelines

Anemia in Patients with Chronic Kidney Disease (CKD)

- An individual is on dialysis

  OR

- An individual is not on dialysis and must meet the following criteria:
  - Has adequate iron stores OR is currently receiving iron therapy;
  - *For an initial authorization* – must have a hemoglobin <10.0 g/dL for 18 years of age or older OR a hemoglobin ≤11.0 g/dL for less than 18 years of age;
  - *For individuals who are currently receiving an erythropoiesis-stimulating agent (e.g., an epoetin alfa product [e.g., Epogen, Procrit, or Retacrit], a darbepoetin alfa product [e.g., Aranesp], a methoxy polyethylene glycol-epoetin beta product [e.g., Mircera])* – must have a hemoglobin. ≤12.0 g/dL.

Anemia associated with zidovudine use in HIV-infected patients

- Is currently receiving zidovudine therapy
- Has adequate iron stores OR is currently receiving iron therapy
- *For an initial authorization* – must have a hemoglobin <10.0 g/dL OR has a serum erythropoietin level ≤500 mU/mL
- *For individuals who are currently receiving an erythropoiesis-stimulating agent (e.g., an epoetin alfa product [e.g., Epogen, Procrit, or Retacrit], a darbepoetin alfa product [e.g., Aranesp])* – must have a hemoglobin ≤12.0 g/dL

Reduction of allogeneic red blood cell transfusion in patients undergoing surgery

The individual must meet ALL of the following criteria:

- Has a hemoglobin ≤13.0 g/dL
- The surgery is elective, nonvascular, and noncardiac

- Is not willing or able to donate autologous blood prior to surgery
- Has adequate iron stores OR is currently receiving iron therapy

Approval Duration: 1 month (for surgery) and 12 months (for all other indications)

Dosing Recommendations

Anemia associated with chronic kidney disease (CKD)
The recommended initial dose is 50 to 100 units/kg 3 times weekly in adults and 50 units/kg 3 times weekly in pediatric patients. Intravenous route is recommended for patients on hemodialysis.

Zidovudine-associated anemia in HIV-infected patients
The recommended dose is 100 units/kg 3 times weekly.

Reduction of allogeneic blood transfusion requirements in anemic surgery patients
The recommended dose is 300 units/kg per day daily for 15 days or 600 units/kg weekly.

References

1. Procrit® injection for intravenous or subcutaneous use [prescribing information]. Horsham, PA: Janssen; April 2024
2. Epogen® injection for intravenous or subcutaneous use [prescribing information]. Thousand Oaks, CA: Amgen, Inc.; December 2024.
3. Retacrit™ injection for subcutaneous or intravenous use [prescribing information]. New York, NY and Lake Forest, IL: Pfizer and Hospira; June 2024.
4. Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. *Kidney Int*. 2012; 2(Suppl):279-335.